

**REMARKS**

The parent application (U.S. Patent Appln. Ser. No. 09/314,847, filed May 19, 1999, now U.S. Patent No. 6,365,410) was originally filed with 48 Claims. Patent No. 6,365,410 contains Claims that correspond to Claims 1-3, 11-24, and 28-48 of the originally filed application. In the transmittal letter that was filed with the present Divisional application, Applicants requested that Claims 1-3, 11-24, and 28-48 be cancelled. As this request was not entered, Applicants submit that at the time of the Restriction Requirement mailed October 1, 2002, all 48 Claims were pending. In a Response mailed October 23, 2002, Applicants cancelled Claims 1-3, 11-24 and 28-48, as well as cancelled Claims 4-10, and 25-27, and added new Claims 49-58, which correspond to cancelled Claims 4-10 and 25-27. All of the cancelled Claims were cancelled without prejudice. Thus, at the time of the present Office Action, Claims 49-58 were pending.

In the present Response, the Specification has been amended in accordance with 37 C.F.R. §1.821 through 1.825 to add the Sequence Listing. No new matter is introduced by way of these amendments. Although the Specification was previously amended to add the Sequence Identification Numbers, it is respectfully requested that the present amendments be entered and replace those previously requested as these amendments correspond to the Sequence Listing herewith provided.

Applicants note that the Examiner has indicated that Claims 50-52, 54 and 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening Claims. The Examiner's rejections are addressed in the following order:

- 1) Claims 49 and 55 stand rejected under the judicially-created doctrine of obviousness-type double patenting, as being allegedly unpatentable over Claim 3 of U.S. Patent No. 6,365,410;
- 2) Claim 53 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite; and
- 3) Claim 53 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement.

**1) There is No Double-Patenting**

The Examiner has rejected Claims 49 and 55 under the judicially-created doctrine of obviousness-type double patenting, as being allegedly unpatentable over Claim 3 of U.S. Patent No. 6,365,410 ("410 Patent"). In particular, the Examiner argues that Claims 49 and 50 herein, as well as Claim 3 of the '410 Patent, recite a method for preparing an evolved microorganism containing a heterologous protein. The Examiner argues that Claims 49 and 55 cannot be considered patentably distinct over Claim 3 of the '410 Patent when there is a specifically recited embodiment in Claim 3 (i.e., the heterologous protein is an enzyme) that would anticipate Claim 49 or 50. In order to further their business interests and the present application, yet without acquiescing to the Examiner's arguments, Applicants will submit a Terminal Disclaimer upon receiving notification that the Claims are allowed.

**2) The Claims Are Definite**

The Examiner has rejected Claim 53 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner indicates that "[t]he mutator gene cannot be selected from the group consisting of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU* as these genes are wild-type and according to the invention a mutator gene is a repair gene with a mutation." (Office Action, page 5). Although Applicants respectfully submit that the Claim is definite as filed, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, Applicants have amended Claim 53 to remove the recitation of these wild-type genes. Applicants expressly reserve the right to prosecute the originally filed, similar and/or broader Claims in additional application(s).

**3) The Written Description is Met**

The Examiner has rejected Claim 53, under 35 U.S.C. §112, first paragraph, as allegedly not meeting the written description requirement. In particular the Examiner argues that "applicants only disclose *mutD* mutations, but do not disclose homologues of *mutD* or mutations or homologues of other *mut* genes. . . . Given the diversity of the recited mutator genes, the absence of disclosed or art recognized structure-function relationships and the unpredictability of the art, the disclosure of one example in one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus." (Office Action, pages 5-6). Applicants must respectfully

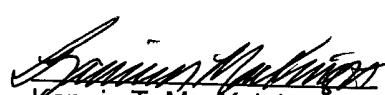
disagree. The presently rejected Claim is a *method* Claim for preparing an evolved microorganism that includes the use of a mutator gene. The Claims are not directed toward mutator genes themselves, as they are only a component used in the present method Claim. The method is clearly set forth in the Specification and the sequences of the *mutD*, *mutt*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, and *mutU* genes are described in the preset Specification (See e.g., the section "II. Mutator genes and frequency of mutations," beginning on page 12, of the Specification as filed). The choice of a specific *mut* gene is irrelevant to the performance of the method, as any of the mutator genes described herein. Indeed, it is intended that the presently claimed invention encompass the use of at least one of the mutant DNA repair genes and may involve more than one (See, page 12, lines 24-25). Applicants respectfully submit that the more detailed disclosure of the methods involving *mutD* do not render the use of the methods with other mutator genes unpatentable. As the method is clearly set forth in the Specification and the Specification clearly teaches the use of these mutator genes, Applicants respectfully submit that the Claims meet the written description requirement and request that this rejection be withdrawn.

## CONCLUSION

In light of the above remarks, the Applicants believe the pending claims are in condition for allowance and issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application and/or if there are any questions regarding the present Response and/or application, the Examiner is invited to telephone the undersigned at (650) 846-5838.

Respectfully submitted,

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